Complete Summary

GUIDELINE TITLE

Diagnosis and management of chronic kidney disease.

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of chronic kidney disease. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2008. 50 p. (SIGN publication; no. 103). [250 references]

GUIDELINE STATUS

This is the current release of the guideline.

Any amendments to the guideline in the interim period will be noted on Scottish Intercollegiate Guidelines Network (SIGN) Web site.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- November 8, 2007 and January 3, 2008 Update, Erythropoiesis Stimulating Agents (ESAs): The U.S. Food and Drug Administration (FDA) notified healthcare professionals of revised boxed warnings and other safety-related product labeling changes for erythropoiesis-stimulating agents (ESAs) stating serious adverse events, such as tumor growth and shortened survival in patients with advanced cancer and chronic kidney failure.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Chronic kidney disease

GUIDELINE CATEGORY

Diagnosis
Management
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Geriatrics
Internal Medicine
Nephrology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Health Care Providers
Hospitals
Nurses
Occupational Therapists
Patients
Pharmacists
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Public Health Departments
Students

GUIDELINE OBJECTIVE(S)

- To help identify which individuals are more likely to develop chronic kidney disease (CKD)
- To provide guidance on how to diagnose CKD principally using blood and urine tests
- To make recommendations on how to slow the progression of CKD and how to reduce the risk of cardiovascular disease

TARGET POPULATION

Adult patients (≥ 18 years) with chronic kidney disease

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Risk Assessment

1. Regular renal function surveillance of high risk patients (e.g., smokers, patients with diabetes, hypertension, cardiovascular disease, etc.)
2. Albumin/creatinine ratio and protein/creatinine ratio to detect and monitor kidney damage
3. Evaluation for urinary tract infection and malignancy
4. Ultrasound of renal tract
5. Prediction equations to assess glomerular filtration rate (GFR)
6. Classification of chronic kidney disease
7. Clinical evaluation and referral

Treatment

1. Antihypertensive treatment
2. Angiotensin converting enzyme (ACE) inhibitors and/or angiotensin receptor blockers (ARBs) to reduce proteinuria and progression of chronic kidney disease
3. Non-dihydropyridine calcium channel blockers
4. Lipid lowering statin therapy
5. Aspirin or other low-dose antiplatelet therapy
6. Dietary modification (e.g., a reduction in sodium)
7. Lifestyle modification
8. Pre-dialysis psychoeducation
9. Managing anemia
10. Monitoring nutritional status to prevent malnutrition and obesity
11. Managing renal bone disease
12. Managing metabolic acidosis

MAJOR OUTCOMES CONSIDERED

- Incidence of chronic kidney disease
- Incidence of cardiovascular disease
- Incidence of end stage renal disease
- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The evidence base for this guideline was synthesised in accordance with Scottish Intercollegiate Guidelines Network (SIGN) methodology. A systematic review of the literature was carried out using a search strategy devised by a SIGN Information Officer. Databases searched include Medline, Embase, Cinahl, PsycINFO and The Cochrane Library. For most searches the year range covered was 2000-2006, but some went back to 1995. Internet searches were carried out on various websites including the New Zealand Guidelines Programme, National Electronic Library for Health (NELH) Guidelines Finder, and the US National Guideline Clearinghouse. The Medline version of the main search strategies can be found on the SIGN website, in the section covering supplementary guideline material. The main searches were supplemented by material identified by individual members of the development group.

At the start of the guideline development process, a SIGN Information Officer conducted a literature search for qualitative and quantitative studies that addressed patient issues relevant to chronic kidney disease. The search was run in Medline, Embase, CINAHL and PsycINFO, and the results were summarised and presented to the guideline development group.

Most of the literature focused on dialysis and transplantation. However, some of the themes identified could be extrapolated to the predialysis stage, the main ones being 'information needs', 'adherence to diet regimens' and 'emotional impact'. A copy of the Medline version of the patient search strategy is available on the SIGN website.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies
High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies (e.g., case reports, case series)

4: Expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. The result of this assessment will affect the level of evidence allocated to the paper, which will in turn influence the grade of recommendation that it supports.

The methodological assessment is based on a number of key questions that focus on those aspects of the study design that research has shown to have a significant influence on the validity of the results reported and conclusions drawn. These key questions differ between study types, and a range of checklists is used to bring a degree of consistency to the assessment process. Scottish Intercollegiate Guidelines Network (SIGN) has based its assessments on the Method for Evaluating Research and Guideline Evidence (MERGE) checklists developed by the New South Wales Department of Health, which have been subjected to wide consultation and evaluation. These checklists were subjected to detailed evaluation and adaptation to meet SIGN's requirements for a balance between methodological rigour and practicality of use.

The assessment process inevitably involves a degree of subjective judgment. The extent to which a study meets a particular criterion (e.g., an acceptable level of loss to follow up) and, more importantly, the likely impact of this on the reported results from the study will depend on the clinical context. To minimise any potential bias resulting from this, each study must be evaluated independently by at least two group members. Any differences in assessment should then be discussed by the full group. Where differences cannot be resolved, an independent reviewer or an experienced member of SIGN Executive staff will arbitrate to reach an agreed quality assessment.

Evidence Tables

Evidence tables are compiled by SIGN executive staff based on the quality assessments of individual studies provided by guideline development group members. The tables summarise all the validated studies identified from the systematic literature review relating to each key question. They are presented in a standard format to make it easier to compare results across studies, and will present separately the evidence for each outcome measure used in the published

studies. These evidence tables form an essential part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]), available from the SIGN Web site.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Synthesising the Evidence

Guideline recommendations are graded to differentiate between those based on strong evidence and those based on weak evidence. This judgment is made on the basis of an (objective) assessment of the design and quality of each study and a (perhaps more subjective) judgment on the consistency, clinical relevance and external validity of the whole body of evidence. The aim is to produce a recommendation that is evidence-based, but which is relevant to the way in which health care is delivered in Scotland and is therefore implementable.

It is important to emphasise that the grading does not relate to the importance of the recommendation, but to the strength of the supporting evidence and, in particular, to the predictive power of the study designs from which that data was obtained. Thus, the grading assigned to a recommendation indicates to users the likelihood that, if that recommendation is implemented, the predicted outcome will be achieved.

Considered Judgment

It is rare for the evidence to show clearly and unambiguously what course of action should be recommended for any given question. Consequently, it is not always clear to those who were not involved in the decision making process how guideline developers were able to arrive at their recommendations, given the evidence they had to base them on. In order to address this problem, SIGN has introduced the concept of considered judgment.

Under the heading of considered judgment, guideline development groups summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- External validity (generalisability) of study findings
- Directness of application to the target population for the guideline
- Any evidence of potential harms associated with implementation of a recommendation

- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources needed to treat them in accordance with the recommendation)
- Whether, and to what extent, any equality groups may be particularly advantaged or disadvantaged by the recommendations made
- Implementability (i.e., how practical it would be for the NHS in Scotland to implement the recommendation)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgment. Once they have considered these issues, the group is asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

Additional detail about SIGN's process for formulating guideline recommendations is provided in Section 6 of the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the SIGN Web site.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A: At least one meta-analysis, systematic review of randomized controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; *or*

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group

COST ANALYSIS

The guideline developers reviewed published cost analyses.

In addition, the National Institute for Health and Clinical Excellence has developed a budgetary impact model for its guideline on anemia in people with chronic kidney disease (CKD). This model provides estimates of the prevalence of anemia by stage of CKD in people who are not on dialysis. Further details can be found in section 5.1.1 of the original guideline document.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A national open meeting is the main consultative phase of SIGN guideline development, at which the guideline development group presents its draft recommendations for the first time. The national open meeting for this guideline was held on 22 June 2006 and was attended by 144 representatives of all the key specialties relevant to the guideline. The draft guideline was also available on the SIGN website for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline.

Peer Review

All SIGN guidelines are reviewed in draft form by independent expert referees, who are asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. A number of general practitioners (GPs) and other primary care practitioners also provide comments on the guideline from the primary care perspective, concentrating particularly on the clarity of the recommendations and their assessment of the usefulness of the guideline as a working tool for the primary care team. The draft is also sent to a lay reviewer in order to obtain comments from the patient's perspective. The comments received from peer reviewers and others are carefully tabulated and discussed with the chairman and with the guideline development group. Each point must be addressed and any changes to the guideline as a result noted or, if no change is made, the reasons for this recorded.

As a final quality control check prior to publication, the guideline and the summary of peer reviewers' comments are reviewed by the SIGN Editorial Group for that guideline to ensure that each point has been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised. Each member of the guideline development group is then asked formally to approve the final guideline for publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the full-text guideline document.

The grades of recommendations (A–D) and levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Risk Factors, Diagnosis and Classification

Detection of Individuals at Higher Risk of Developing Chronic Kidney Disease

Diabetes Mellitus

D - All patients with diabetes should have regular surveillance of renal function.

Smoking

C - Smoking should be considered as a risk factor for the development of chronic kidney disease.

Obesity and Socioeconomic Status

C - Low socioeconomic status should be considered as a risk factor for the development of chronic kidney disease.

Detecting Kidney Damage

Proteinuria

B - In patients with diabetes, albumin/creatinine ratio may be used to exclude diabetic nephropathy.

C - Albumin/creatinine ratio is recommended for detecting and monitoring diabetic nephropathy.

B - In patient groups with a high prevalence of proteinuria without diabetes, protein/creatinine ratio may be used to exclude chronic kidney disease.

D - In patients with established chronic kidney disease and without diabetes, measurement of protein/creatinine ratio may be used to predict risk of progressive disease.

Haematuria

D - Patients with persisting isolated microscopic haematuria should be initially evaluated for urinary tract infection and malignancy.

Comparing Renal Function Tests

C - Where an assessment of glomerular filtration rate is required prediction equations should be used in preference to 24-hour urine creatinine clearance or serum creatinine alone.

Treatment

Lowering Blood Pressure

A - Blood pressure should be controlled to slow the deterioration of glomerular filtration rate and reduce proteinuria. Patients with ≥1 g/day of proteinuria (*approximately equivalent to a protein/creatinine ratio of 100 mg/mmol*) should have a target maximum systolic blood pressure of 130 mmHg.

Reducing Proteinuria

A - Patients with chronic kidney disease and proteinuria should be treated to reduce proteinuria.

Angiotensin Converting Enzyme (ACE) Inhibitors and Angiotensin Receptor Blockers (ARBs)

Reducing the Progression of Chronic Kidney Disease

Progression of Microalbuminuria to Macroalbuminuria in Diabetes Mellitus

A - Patients with chronic kidney disease and type 1 diabetes with microalbuminuria should be treated with an ACE inhibitor irrespective of blood pressure.

A - Patients with chronic kidney disease and type 2 diabetes with microalbuminuria should be treated with an ACE inhibitor or an ARB irrespective of blood pressure.

Proteinuria Reduction in Non-diabetic Patients with Chronic Kidney Disease

A - ACE inhibitors and ARBs are the agents of choice to reduce proteinuria in patients without diabetes but who have chronic kidney disease and proteinuria.

Combination Treatment with ACE Inhibitors and ARBs

A - ACE inhibitors and/or ARBs should be used as agents of choice in patients (*with or without diabetes*) with chronic kidney disease and proteinuria (*≥0.5 g/day, approximately equivalent to a protein/creatinine ratio of 50 mg/mmol*) in order to reduce the rate of progression of chronic kidney disease.

Non-Dihydropyridine Calcium Channel Blockers

Reducing the Progression of Chronic Kidney Disease

A - Non-dihydropyridine calcium channel blockers should be considered in patients with chronic kidney disease and proteinuria who are intolerant of ACE inhibitors or ARBs.

Lipid Lowering

Reducing the Risk of Cardiovascular Disease

B - Statin therapy should be considered in all patients with stage 1-3 chronic kidney disease, with a predicted 10-year cardiovascular risk ≥ 20%.

Antiplatelet Therapy

Reducing the Risk of Cardiovascular Disease

B - Low-dose antiplatelet therapy should be considered in all patients with stage 1-3 chronic kidney disease, whose estimated 10-year cardiovascular risk is ≥ 20%.

Dietary Modification

Reducing the Progression of Chronic Kidney Disease

Protein Restrictions

A - Dietary protein restrictions (*<0.8 g/kg/day*) are not recommended in patients with early stages of chronic kidney disease (*stages 1-3*).

Reducing the Risk of Cardiovascular Disease

B - For patients with stage 1-4 chronic kidney disease and hypertension a reduction in sodium (*<2.4 g/day or <100 mmol/day which is equivalent to <6 g of salt*) is recommended as part of a comprehensive strategy to lower blood pressure and reduce cardiovascular risk.

Treatments to Improve Quality of Life

Psychosocial Management

Patient Education

B - The delivery of a psychologically informed, pre-dialysis psychoeducation programme is recommended for all patients with progressive chronic kidney disease at any stage who will eventually require renal replacement therapy.

Erythropoiesis Stimulating Agents in the Management of Anaemia

A - Erythropoiesis stimulating agents should be considered in all patients with anaemia of chronic kidney disease to improve their quality of life.

D - Nutritional status (*height, weight, body mass index, percentage weight loss*) should be monitored in all patients with chronic kidney disease at stage 3 or higher.

Definitions:

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Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

CLINICAL ALGORITHM(S)

An algorithm for screening, assessment and diagnosis of patients with chronic kidney disease is provided in the original guideline document.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis and management of chronic kidney disease

POTENTIAL HARMS

Side effects of angiotensin converting enzyme inhibitors (ACE inhibitors), angiotensin II receptor blockers (ARBs), statins, antiplatelet therapy, and erythropoiesis stimulating agents.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgement should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is, however, advised that significant

departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.

- The management of patients with end stage renal disease (ESRD) or patients with acute kidney disease is excluded from this guideline. Patients with clinical features suggestive of a primary renal diagnosis, e.g., glomerulonephritis presenting with nephrotic syndrome, or renal disease secondary to vasculitis presenting with haematuria and proteinuria, should be referred to the renal service. Their specific management is not part of this guideline. The management of complications associated with chronic kidney disease (CKD) during pregnancy is a specialised area which is not covered in this guideline.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation of national clinical guidelines is the responsibility of each National Health Service (NHS) Board and is an essential part of clinical governance. Mechanisms should be in place to review care provided against the guideline recommendations. The reasons for any differences should be assessed and addressed where appropriate. Local arrangements should then be made to implement the national guideline in individual hospitals, units and practices.

A first step in implementing a clinical practice guideline is to gain an understanding of current clinical practice. Audit tools designed around guideline recommendations can assist in this process. Audit tools should be comprehensive but not time consuming to use. Successful implementation and audit of guideline recommendations requires good communication between staff and multidisciplinary team working. The guideline development group has identified key points to audit to assist with the implementation of this guideline.

Resource implications of key recommendations are detailed in section 5.1 of the original guideline document.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Clinical Algorithm
Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of chronic kidney disease. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2008. 50 p. (SIGN publication; no. 103). [250 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008

GUIDELINE DEVELOPER(S)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Scottish Executive Health Department

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Guideline Development Group: Professor Alison MacLeod, Consultant Nephrologist, Aberdeen Royal Infirmary (*Chair*); Dr Tariq Ali, Research Associate, Aberdeen Royal Infirmary; Dr Gordon Allan, General Practitioner, Methil; Mrs Jane Bryce, Scottish Patients Advisory Group, Kidney Research UK; Mrs Hazel Elliott, Dietitian, Edinburgh Royal Infirmary; Dr Nicholas Fluck, Consultant Nephrologist, Aberdeen Royal Infirmary; Dr Jane Goddard, Consultant Nephrologist, Edinburgh Royal Infirmary; Dr John Hunter, Consultant Physician and Rheumatologist, Gartnavel General Hospital, Glasgow; Mrs Joanna Kelly, Information Officer, SIGN; Dr Mark MacGregor, Consultant Nephrologist, Crosshouse Hospital, Kilmarnock; Ms

Shonaid McCabe, Clinical Specialist in Occupational Therapy, Monklands Hospital, Airdrie; Dr Michael J Murphy, Senior Lecturer in Biochemical Medicine, University of Dundee; Dr Moray Nairn, Programme Manager, SIGN; Ms Maureen Perry, Clinical Nurse Specialist, Renal Unit, Ninewells Hospital, Dundee; Dr Maria K Rossi, Consultant in Public Health, NHS Grampian; Dr Diana Johnston, General Practitioner, Dundee; Ms Shelagh Salter, Physiotherapist, Edinburgh Royal Infirmary; Ms Sara Smith, Undergraduate Programme Leader – Dietetics, Queen Margaret University, Edinburgh; Dr Casey Stewart, Clinical Director - Acute Medicine, Edinburgh Royal Infirmary; Dr Mark Strachan, Consultant Physician, Western General Hospital; Ms Morag Whittle, Renal Pharmacist, Glasgow Royal Infirmary; Dr Matt Wild, Consultant Clinical Psychologist, Glasgow Royal Infirmary

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the guideline development group made declarations of interest and further details of these are available on request from the SIGN Executive.

GUIDELINE STATUS

This is the current release of the guideline.

Any amendments to the guideline in the interim period will be noted on Scottish Intercollegiate Guidelines Network (SIGN) Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Quick reference guide: Diagnosis and management of chronic kidney disease. Scottish Intercollegiate Guidelines Network, 2008. 2 p. Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.
- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network. (SIGN publication; no. 50). Available from the SIGN Web site.
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research & Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site.

PATIENT RESOURCES

A sample information leaflet for patient is provided in the original guideline document.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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Date Modified: 11/3/2008